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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:

Richard S. Dondero, et al.

Application No.: 10/684,774

Filing Date: October 14, 2003

For: INTERLEUKIN-1 MUTEINS USEFUL AS VACCINE

Confirmation No.: Not Yet Assigned

Group Art Unit: Not Yet Assigned

Examiner: Not Yet Assigned

DATE OF DEPOSIT: November 19, 2003

I HEREBY CERTIFY THAT THIS PAPER IS BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE AS FIRST CLASS MAIL, POSTAGE PREPAID, ON THE DATE INDICATED ABOVE AND IS ADDRESSED TO THE UNITED STATES PATENT AND TRADEMARK OFFICE, P.O. BOX 1450, ALEXANDRIA, VA 22313-1450.

*Elizabeth A. McLoud*

TYPED NAME: Elizabeth A. McLoud

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

INFORMATION DISCLOSURE STATEMENT

Pursuant to 37 CFR § 1.56 and in accordance with 37 CFR §§ 1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 CFR § 1.56(b).



In accordance with § 1.97(b), since this Information Disclosure Statement is being filed either within three months of the filing date of the above-identified application, within three months of the date of entry into the national stage of the above identified application as set forth in § 1.491, before the mailing date

of a first Office Action on the merits of the above-identified application, or before the mailing date of a first Office Action after the filing of request for continued examination under § 1.114, no additional fee is required.

- ☐ In accordance with § 1.129(a), this Information Disclosure Statement is being filed in connection with ☐ the first or ☐ second After Final Submission, therefore:

☐ Certification in Accordance with § 1.97(e) is attached; or

☐ The fee of \$180.00 as set forth in § 1.17(p) is attached.

- ☐ In accordance with § 1.97(c), this Information Disclosure Statement is being filed after the period set forth in § 1.97(b) above but before the mailing date of either a Final Action under § 1.113 or a Notice of Allowance under § 1.311, or before an action that otherwise closes prosecution in the application, therefore:

☐ Certification in Accordance with § 1.97(e) is attached;

or

☐ The fee of \$180.00 as set forth in § 1.17(p) is attached.

- ☐ In accordance with § 1.97(d), this Information Disclosure Statement is being filed after the mailing date of either a Final Action under § 1.113 or a Notice of Allowance under § 1.311 but before, or simultaneously with, the payment of the Issue Fee, therefore included are: Certification in Accordance with § 1.97(e); and the submission fee of \$180.00 as set forth in § 1.17(p).

- ☐ Copies of each of the references listed on the attached Form PTO-1449 are enclosed herewith.

- ☒ Copies of references listed on the attached Form PTO-1449 are enclosed herewith
- ☒ Copies of references listed on the attached Form PTO 1449 are not required to be submitted pursuant to the June 30, 2003 recent revisions to 37 CFR § 1.98(a)(2)(i).

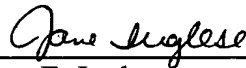
EXCEPT THAT:

- ☐ In view of the voluminous nature of references [list as appropriate], and the likelihood that these references are available to the Examiner, copies are not enclosed herewith.
- ☒ In accordance with § 1.98(d), copies of the following references listed on the attached Form PTO-1449 are not enclosed herewith because they were previously cited by or submitted to the U.S. Patent and Trademark Office in patent application(s) for which a claim for priority under 35 U.S.C. § 120 have been made in the instant application:
  - ☒ Copies of references 1-37 listed on the attached Form PTO-1449 were previously cited by or submitted to the Patent and Trademark Office in prior Application No. 09/729,509, filed December 14, 2000.

Please charge any deficiency or credit any overpayment to Deposit Account No. 23-3050. This form is submitted in duplicate.

- ☐ The relevance of those listed references which are not in the English language is as follows:
- ☒ There are no listed references which are not in the English language.

Date: *November 19, 2003*

  
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<b>Form PTO-1449 Modified</b>  List of Patent and Publications Cited by Applicant (Use several sheets if necessary)  U.S. Department of Commerce Patent and Trademark Office		Docket No. CELL-0276/PA562.div	Application No. 10/684,774
		Applicant Richard S. Dondero, et al.	
		Filing Date October 14, 2003	Group Not Yet Assigned
		Confirmation No. Not Yet Assigned	
<b>OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)</b>			
	1	Boraschi and Tagliabue, "Interleukin-1 and Interleukin-1 Fragments as Vaccine Adjuvants", <i>Methods</i> , <b>1999</b> , 19, 108-113	
	2	Carter, D.B., et al., "Purification, cloning, expression and biological characterization of an interleukin-1 receptor antagonist protein," <i>Nature</i> , April <b>1990</b> , 344, 633-638	
	3	Clore, G.M., "High-resolution three-dimensional structure of inteleukin 1 $\beta$ in solution by three- and four-dimensional nuclear magnetic resonance spectroscopy," <i>Biochemistry</i> , <b>1991</b> , 30(9), 2315-2323	
	4	DeChiara, T.M., et al., "Structure-function analysis of murine interleukin 1: biologically active polypeptides are at least 127 amino acids long and are derived from the carboxyl terminus of a 270-amino acid precursor," <i>Proc. Natl. Acad. Sci.</i> , November <b>1986</b> , 83, 8303-8307	
	5	Dower, S.K., et al., "Detection and characterization of high affinity plasma membrane receptors for human interleukin 1," <i>J. Exp. Med.</i> , <b>1985</b> , 162, 501-515	
	6	Dripps, D.J., et al., "Interleukin-1 (IL-1) receptor antagonist bonds to the 80-kDa IL-1 receptor but does not initiate IL-1 signal transduction," <i>J. Biol. Chem.</i> , June 5, <b>1991</b> , 266(16), 10331-10336	
	7	Driscoll, P.C., et al., "Complete resonance assignment for the polypeptide backbone of interleukin 1 $\beta$ using three-dimensional heteronuclear NMR spectroscopy," <i>Biochemistry</i> , <b>1990</b> , 29(14), 3542-3556	
	8	Finzel, B.C., et al., "Crystal structure of recombinant human interleukin-1 $\beta$ at 2.0 Å resolution," <i>J. Mol. Biol.</i> , <b>1989</b> , 209, 779-791	
	9	Graves, B.J., et al., "Structure of 1 $\alpha$ at 2.7 Å resolution," <i>Biochemistry</i> , <b>1990</b> , 29, 2679-2684	
	10	Gronenborn, et al., "Site directed mutants of human interleukin-1 $\alpha$ : a H-NMR and receptor binding study," <i>Federation of European Biochemical Societies</i> , April <b>1998</b> , 231(1), 135-138	
<b>EXAMINER</b>		<b>DATE CONSIDERED</b>	



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	11	Hannum, C.H., et al., "Interleukin-1 receptor antagonist activity of human interleukin-1 inhibitor," <i>Nature</i> , January 1990, 343, 336-340	
	12	Huang, J.J., et al., "Muteins of human interleukin-1 that show enhanced bioactivities," <i>FEBS Letters</i> , November 1987, 223(2), 294-298	
	13	Jobling, S.A., et al., "Biological activity and receptor binding of human prointerleukin-1 $\beta$ and subpeptides," <i>J. Biol. Chem.</i> , November 5, 1988, 263, 16372-16378	
	14	Ju, G.E., et al., "Conversion of the interleukin 1 receptor antagonist into an agonist by site-specific mutagenesis," <i>Proc. Natl. Acad. Sci. USA</i> , April 1991, 88, 2658-2662	
	15	Kramer, D.R., et al., "Cytokine mediated effects in mucosa immunity," <i>Immunology and Cell Biology</i> , 1995, 73, 389-396	
	16	Lin, et al., "Present status of the use of cytokines as adjuvants with vaccines to protect against infectious diseases," <i>Clinical Infectious Diseases</i> , December 1995, 21, 1439-1449	
	17	Lofthouse, S.A., et al., "Parameters related to the application of recombinant ovine interleukin-1 $\beta$ as an adjuvant," <i>Vaccine</i> , 1995, 13(14), 1277-1287	
	18	MacDonald, H., et al., "Point mutations of human interleukin-1 with decreased receptor binding affinity," <i>FEBS Letters</i> , December 1986, 209(2), 295-298	
	19	McMahan, C.J., et al., "A novel IL-1 receptor cloned from B cells by mammalian expression, is expressed in many cell types," <i>EMBO J</i> , 10(10), 2821-2832	
	20	Mosley, B., et al., "Determination of the minimum polypeptide lengths of the functionally active sites of human interleukins 1 $\alpha$ and 1 $\beta$ ," <i>Proc. Natl. Acad. Sci.</i> , July 1987, 84, 4572-4576	
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	21	Nakai, S. et al., "A Mutant Protein of Human Interleukin-1 $\beta$ with Immunostimulatory But Not Pyrogenic Potency", <i>Life Sciences</i> , <b>1990</b> , 47, 1707-1714	
	22	Nash, A.D., et al., "Recombinant cytokines as immunological adjuvants," <i>Immunology and Cell Biology</i> , <b>1993</b> , 71, 367-379	
	23	Priestle, J.P., et al., "The three-dimensional structure of human interleukin-1 $\beta$ refined to 2.0 A resolution," in <i>Cytokines and Lipocortins in Inflammation and Differentiation</i> , <b>1990</b> , 297-307	
	24	Priestle, J.P., et al., "Crystal structure of the cytokine interleukin-1 $\beta$ ," <i>The EMBO Journal</i> , <b>1988</b> , 7(2), 339-343	
	25	Seckinger, P., et al., "A urine inhibitor of interleukin 1 activity affects both interleukin 1 $\alpha$ and 1 $\beta$ but not tumor necrosis factor $\alpha$ ," <i>J. Immunol.</i> , September 1, <b>1987</b> , 139(5)	
	26	Sims, J.E., et al., "CDNA expression cloning of the IL-1 receptor, a member of the immunoglobulin superfamily," <i>Science</i> , July 29, <b>1988</b> , 241, 585-588	
	27	Spriggs, M.K., et al., "Induction of an interleukin-1 receptor (IL-1R) on monocytic," <i>J. Biol. Chem.</i> , December <b>1990</b> , 265(36), 22499-22505	
	28	Staats and Ennis, "IL-1 Is an Effective Adjuvant for Mucosal and Systemic Immune Responses When Coadministered with Protein Immunogens", <i>The Journal of Immunology</i> , <b>May 15, 1999</b> , 162, 6141-6147	
	29	Staats, H. F. et al., "IL-1 $\beta$ Is an Effective Adjuvant for Nasal Vaccines", <i>Cytokine</i> , <b>November, 1999</b> , 11, 199	
	30	Wu, H.-Y., et al., "Comparison of systemic and mucosal priming for mucosal immune responses to a bacterial protein antigen given with or coupled to cholera toxin (CT) B subunit, and effects of pre-existing anti-CT immunity," <i>Vaccine</i> , <b>1994</b> , 12, 215	
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	31	Young, P., et al., "A site-specific mutant of IL-1 $\beta$ with reduced activity but wild-type binding," <i>Lymphokine Res.</i> , 1990, 9, 599 (Abstract No. 3.55)			
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**U. S. PATENT DOCUMENTS**

Examiner Initial		Document No.	Date	Name	Class	Subclass
	32	5,206,014	04/27/93	Nencioni, et al.		
	33	5,286,847	02/15/94	Gehrke et al.	530	351
	34	5,334,379	08/02/94	Pillai, et al.		
	35	5,503,841	04/02/96	Doyle, et al.		
	36	5,847,098	12/08/98	Nakai et al.	536	23.5

**FOREIGN PATENT DOCUMENTS**

Examiner Initial		Document No.	Date	Country	Translation	
					YES	NO
	37	WO 91/01143	07/16/90	PCT		

**EXAMINER****DATE CONSIDERED**